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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,274	09/24/2001	Jaap Van Der Louw	99469 US	2129

31846 7590 01/29/2003

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MILLSBORO, DE 19966

EXAMINER
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QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/937,274

Applicant(s)

VAN DER LOUW ET AL.

Examiner

Sabiha Naim Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1,3-11 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,3-11 and 14-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 13 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

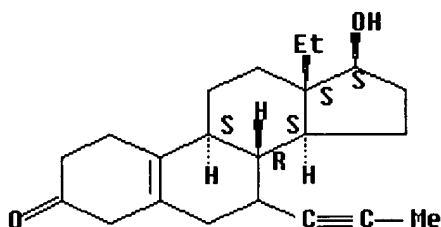
## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Claims 1, 3-11 and 13-16 are pending. Claims 1, 3-11, 14-16 are examined, 13 (drawn to kit) is withdrawn from consideration as non-elected invention. No claim is allowed. Response filed in paper no. 9 and declaration in paper no. 10 is hereby acknowledged. Rejection over Solo et al. is withdrawn on the basis of declaration.

Claims 1, 3 and 4 rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (AN CA62: 1704c, CAOLD).



RN 95171-22-5

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 7-11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear that compound of claim 7 is disclaimed (see proviso in claim 1) why the same compound is claimed in claim 7. It should be canceled.

#### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

#### **Graham Factual Inquiries**

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-11 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardin et al. (US Patent 5,342,834). See the entire document especially abstract of the invention; lines 53-68, col. 6; lines 32-56, col. 2; lines 64-68, col. 3; lines 1-9, col. 4; claims; Table 1; lines 5-68, col. 7;

1. **Determining the scope and contents of the prior art.** Prior art teach that 19NT was metabolized to the reduced product more slowly than testosterone resulting in 22% reduced 19NT. Under similar conditions, 7MNT remained unmetabolized. (see lines 60-68 in col. 6). The failure of 7MNT to undergo 5 $\alpha$  reduction is considered to be due to a steric effect of the 7 $\alpha$  methyl group blocking the interaction of the steroid with the reductase. This effect is expected to occur with 7 $\alpha$ -substituted androgens. Thus these compounds are taught to be superior to other androgens of equivalent potency for use in androgen replacement therapy.

Since 7- $\alpha$  substituted 19-nor testosterone compounds as instantly claimed are taught to be superior for hormone replacement therapy, one having skill in the art would expect to use the similar 19-nor 7 $\alpha$  substituted compounds for the same use such as hormone replacement therapy.

2. **Ascertaining the differences between the prior art and the claims at issue.** Instant claims differ from the reference in claiming 19-nor 7-alkyl and 17 OH substituted steroid. The prior art of record is drawn to structurally similar compounds, which differ, from the compounds embraced by the instant claims in that they are homologue. Instant claims differ from the reference in claiming homologues other than methyl at 7- $\alpha$  position wherein prior art teach an alkyl group at 7 $\alpha$  position (methyl is disclaimed by a proviso in claim 1), other substituents are taught by the prior art.

3. **Resolving the level of ordinary skill in the pertinent art.**

The skilled artisan would have been motivated to prepare additional beneficial steroidal compounds having alkyl group other than methyl group (note, methyl compounds are disclaimed), because it is recognized in the art that homologue are structurally similar and would be expected to possess similar properties. See *Ex parte Henze* (POBA 1948) 83 USPQ 167. Furthermore, prior art

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teach alkyl group at 7-alpha position and discloses that 7-substituted 19-nor compounds can be used for androgen replacement therapy. See also section 2 cited above.

**4. Considering objective evidence present in the application indicating obviousness or nonobviousness.**

Compounds that differ only by the presence of an extra methyl group are homologue. Homologue is of such close structural similarity that the disclosure of a compound renders prima facie obvious its homologue.

The homologue is expected to be prepared by the same method and to have the same properties i.e. useful as an intermediate in the preparation of vitamin D. This expectation is then deemed the motivation for preparing homologue. Homologues are obvious even in the absence of a specific teaching to methylate, *In re Wood* 199 USPQ 137; *In re Hoke* 195 USPQ 148; *In re Lohr* 137 USPQ 548; *In re Magerlein* 202 USPQ 473; *In re Wiechert* 152 USPQ 249; *Ex parte Henkel* 130 USPQ 474; *In re Fauque* 121 USPQ 425; *In re Druey* 138 USPQ 39. In all of these cases, the close structural similarity of two compounds differing by only one (or two) methyl groups sufficed; no specific teaching to methylate was present or required.

Claims 8-11 drawn to formulation would have been obvious to one skilled in the art to prepare additional beneficial compositions. Even in a case where the reference does not teach the same use of the composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393.

Claims 14-16 are drawn to method of treating androgenic deficiency in male would have been obvious to one skilled in the art because 7-alpha alkyl 19-nor testosterone compounds are taught for use as androgen supplementation therapy. The exemplified compound is 7-alpha methyl-19-nor testosterone however, analogues such as ethyl or propyl groups at 7-alpha position would be expected to contain the property for the reasons cited above. Furthermore, Bardin et al teach that 7-alpha substituted androgens should prove superior to other androgens of equivalent potency for use as androgen replacement therapy because they do not undergo amplification via metabolism to 5-alpha reduced product, (see lines 6-24, col. 7). See also lines 25-47 in col. 7 and claims.

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In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Declaration filed by applicants was fully considered however, see page 4 where in conclusion the emphasis is on 7-alpha substituent which is taught by the prior art (Bardin et al.) that these compounds would prove to superior than other androgens. This finding is not considered something unexpected. Compounds having 7-substituent other than alkyl are considered allowable

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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January 26, 2003



SABIHA QAZI, PH.D  
PRIMARY EXAMINER

**Notice of References Cited**

Application/Control No.

09/937,274

Applicant(s)/Patent Under  
Reexamination  
VAN DER LOUW ET AL.

Examiner

Sabiha Naim Qazi

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**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,342,834	08-1994	Bardin et al.	514/178
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.